



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0622]

Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs;
Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs." The draft guidance focuses on the safety aspects in the development and selection of proposed proprietary names for all prescription and nonprescription human drug products and biological products. The draft guidance describes naming design practices to help avoid medication errors and provides a qualitative systematic framework for evaluating proprietary names before submitting them for FDA review. FDA is issuing this draft guidance to help drug and biologic product sponsors develop proprietary names that do not cause or contribute to medication errors or otherwise contribute to the misbranding of the drug.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kellie Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4418, Silver Spring, MD 20993-0002, 301-796-0157, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs." FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors, and has addressed this issue repeatedly in recent decades. Our primary focus has been to develop and communicate to

sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product review and approval process. As part of this initiative, FDA held public meetings in June and December 2003 to discuss the methods used for proprietary name evaluation. In 2007, FDA formally committed to certain performance goals (under the reauthorization of the Prescription Drug User Fee Act (PDUFA IV) (Public Law 110-85), including implementing measures to reduce medication errors related to look-alike and sound-alike proprietary names (PDUFA IV performance goals). In 2008, FDA held a public meeting to further discuss testing and evaluating proprietary names, and initiating a pilot project on proprietary name review. The 2008 meeting focused on advances and current limitations in the science of proprietary name evaluation, FDA's recommendations for best practices in the absence of a "gold standard," and details of the proposed pilot project. The participating expert panel judged all the evaluation methods proposed by FDA to be complementary and of value in the proprietary name testing process. We are issuing this guidance in partial fulfillment of the PDUFA IV performance goals.

This draft guidance document, which addresses minimizing risks through the design of drug product naming, is the last in a series of three guidance documents that FDA is issuing to help sponsors minimize the potential for medication errors when designing and developing products. The first draft guidance, published in the Federal Register on December 13, 2012 (77 FR 74196), focuses on minimizing risks associated with the design of the drug product and its container closure system. The second draft guidance, published in the Federal Register on April 24, 2013 (78 FR 24211), focuses on safety aspects of the container label and carton labeling design.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on best practices for developing and selecting proposed proprietary names to minimize medication errors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Proprietary name information submitted under 21 CFR part 314 has been approved under OMB control number 0910-0001, and proprietary name information submitted under 21 CFR part 601 has been approved under OMB control number 0910-0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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